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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,614

12/03/2004

Kjell Nilsson

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11/26/2007

BUCHANAN, INGERSOLL & ROONEY PC

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EXAMINER

DAVIS, RUTH A

ART UNIT

PAPER NUMBER

1651

NOTIFICATION DATE

DELIVERY MODE

11/26/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/516,614

Applicant(s)

NILSSON, KJELL

Examiner

Ruth A. Davis

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-35 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 and 17-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and response filed on September 18, 2007 has been received and entered into the case. Claim 15 is canceled. Claims 1 – 14 and 16 – 35 are pending; claims 9 – 14 and 17 – 35 are withdrawn; claims 1 – 8 and 16 have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

Rejected under 35 U.S.C. 112, second paragraph, are withdrawn due the amendment.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 – 8 and 16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsson et al. (US 5015576) and/or Nilsson et al. (US 4935365) in view of Morse et al. (US 4123382).

Applicant claims a method for preparing a spheroid gelatin material with continuous pore structure, the method comprising preparing a homogenous water based gelatin solution; adding

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emulsifier with HLB value greater than 9; adding a composition comprising organic solvent and emulsifier with HLB value greater than 9; adding a second composition comprising organic solvent and emulsifier with HLB value less than 8; and allowing the gelatin to solidify. The gelatin is further cross-linked with a chemical compound that is selected from a particular group; the first emulsifier is selected from Tween 80, 40, Myrj 52 and Brji 58; the second is selected from Span 85, 65, and Atmos; the solvent is selected from cyclohexane, toluene, paraffin oil and industrial benzene; specifically cyclohexane. Applicant additionally claims a method for preparing a cast, 3D porous structure, the method comprising preparing a homogenous water based gelatin solution; adding emulsifier with HLB value greater than 9; adding a composition comprising organic solvent and emulsifier with HLB value greater than 9; and casting the solution into a mold. The method further comprises cross-linking the material.

Nilsson (576) and Nilsson (365) each teach methods for preparing gelatin beads (spheres) wherein the method comprises combining gelatin with water, adding Tween 80, followed by adding toluene with Span 85 (examples). The solution is then allowed to solidify (examples). The solutions are further cross-linked with glutaraldehyde (examples).

The references do not teach the methods wherein an additional separate step of adding a combination of emulsifier with HLB greater than 9 and solvent is practiced. However, the references clearly teach that the gel beads/spheres are created by combining the instantly claimed components together and allowing the resulting solution to solidify. Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients together with a reasonable expectation for successfully preparing a porous gelatin sphere.

The references do not teach the method wherein the solvent is cyclohexane. However, the references clearly teach that organic solvents are used (examples). At the time of the claimed invention, cyclohexane was a well known and used organic solvent in the art for making gelatin beads/spheres. In support, Morse teaches methods for making gelatin capsules wherein gelatin is combine with cyclohexane (3-4). Thus as evidenced by the cited art, it would have been obvious to one of ordinary skill in the art to use cyclohexane in the methods of Nilsson with a reasonable expectation for successfully preparing a gelatin material.

Response to Arguments

Applicant argues that the references do not teach the step of adding a solvent with an emulsifier with an HLB greater than 9; and that this step provides an unexpected result in that the resulting structure is highly porous with interconnected pores.

However, this argument fails to persuade because the Nilsson references both teach that combining the claimed emulsifiers and solvents to a gelatin solution results in a spheroid gelatin structure that is highly porous (col.2-4). Thus, such a porous gelatin product does not appear to be an unexpected result, but in fact expected as it is taught in the art.

Therefore the claims stand rejected.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 -3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth A. Davis/
Primary Examiner
Art Unit 1651

November 16, 2007